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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,569	06/14/2001	Pushpa Khanna	U 013488-3	5858

140 7590 07/15/2003

LADAS & PARRY
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
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1653

15

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/881,569

Applicant(s)

KHANNA, PUSHPA

Examiner

Sheridan K Snedden

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 2-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper #14, filed 21 April 2003. Applicant's amendment of claim 1 is acknowledged. Claim 1 is under examination.

Withdrawal of Objections and Rejections

2. The objections and/or rejections not explicitly restated or stated below are withdrawn.

Maintained Objections and Rejections

Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in India (560/DEL/99 and 561/DEL/99) on April 13, 1999. It is noted, however, that applicant has not filed a certified copy of the 560/DEL/99 and 561/DEL/99 application as required by 35 U.S.C. 119(b).

This application repeats a substantial portion of prior Application No. PCT/IN99/00052, filed September 28, 1999, and adds and claims additional disclosure not presented in the prior application. Priority to PCT/IN99/00052 filed on 09/28/1999 is not granted as the table in claim 1 of the instant application is not supported in the priority document. The priority date of the instant application is June 14, 2001.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on April 10, 2002 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The table used in claim 1 does not clearly define protein the for the following reasons:

a. The recitation of amounts and percents (i.e, aaa936 avg nmoles, ugrams, mole percent, and # resiuiues) in the table headings are not clear. Are these table headings to be interpreted as limiting the amino acids to specific amounts or does the claim encompass the recited amino acids in unspecified amounts?

Applicant has amended the claim to indicate that this column represents the sample size used for the analysis. Unfortunately, the information of this column fails to clarify the structure of the peptide or provide a description of the peptide in a definite manner.

b. The use of "pro+cys" is unclear because the amount of each is not specified and could essentially be interpreted as only "pro" or "cys".

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Applicant has amended the claim to indicate the presence of pro-cysteine and cystein. However, it is still unclear as to which of the above and in what amounts are present in the peptide. Additionally, it is unclear how pro-cysteine would be present in a naturally occurring peptide.

c. The meaning of the parentheses used in the table is unclear.

Applicant has failed to provided clarity to this issue.

d. It is not clear what data in the table should literally be used as a claim limitation and what is not relevant.

e. Does the protein contain "trp"?

Applicant has amended the table to indicate that the amount of TRP could not be determined by the amino acid analyzer. Applicant argues of page 4, line 2 of the response, that the protein does contain Trp. However, this information is not reflected in the claim which indicates that the presence could not be determined. As the peptide contains Trp, it is not clear in the claim as to what amount of Trp is found in the peptide. As such, the lack of clear structure renders the claim indefinite.

f. Does the protein contain 160 residues or is this the sample size?

Applicant argues that protein contains a total of 160 amino acids. However, the column represents amino acids in fractions. It is unclear how a peptide would have 4.8 residues of Thr or 11.6 residues of Ala, for example. As such, the lack of clear structure renders the claim indefinite.

7. Note also that "capable of" does not equate to must invariably occur; and, thus the claims are indefinite as indicating only a potential function/action.

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Applicant argues that the use of "capable of" does not render the claims indefinite. This argument is not persuasive because "capable of" does not equate to must invariably occur. As such, an optional function is recited that fails to further limit the claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for

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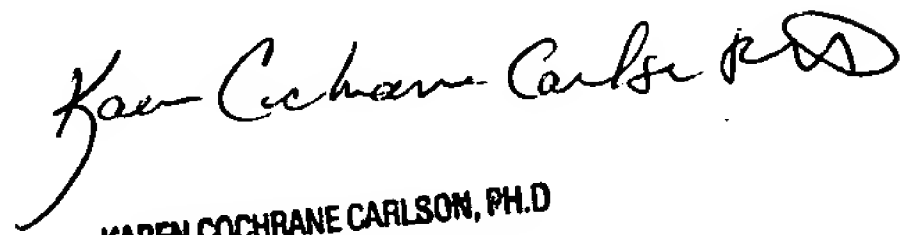
regular communications to the organization where this application or proceeding is assigned is
(703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS

June 19, 2003

SKS


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER